



Department of Vermont Health Access
312 Hurricane Lane, Suite 201
Williston, Vermont 05495

Hep C
FORM#28
C: 1.15
Agency of Human Services

HEPATITIS C TREATMENT Prior Authorization Request Form

In order for beneficiaries to receive coverage for Hepatitis C Treatment, it will be necessary for the prescriber to complete and fax this prior authorization request to Goold Health Systems. Please complete this form in its entirety and sign and date below. Incomplete requests will be returned for additional information. For questions, please contact the GHS help desk at 1-844-679-5363.

Submit request via: Fax: 1-844-679-5366

Prescribing physician:

Name: _____
Physician NPI: _____
Phone#: _____
Fax#: _____
Address: _____
Contact Person at Office: _____

Beneficiary:

Name: _____
Medicaid ID#: _____
Date of Birth: _____ Sex: _____
Pharmacy Name: _____
Pharmacy NPI: _____
Pharmacy Phone: _____ Pharmacy Fax: _____

Hepatitis C treatment PA requests will be approved for members who meet the following guidelines. This PA form will cover up to twelve weeks of therapy. Only a 14 day supply will be allowed for the 1st fill. The first and second pages list the various regimens and the clinical situations for which they will be considered medically necessary according to criteria, as well as the required supporting documentation. The PA must be approved prior to the 1st dose. Documentation of adherence (viral load changes or progress notes with a documented compliance discussion with details on compliance to date) will be required for continuation of therapy beyond 12 weeks & must be submitted with the PA request prior to completing the third month of therapy. For all therapies, member must have documentation of liver fibrosis of at least Metavir stage 3 or 4.

<input type="checkbox"/>	Genotype 1a
<input type="checkbox"/>	Treatment naïve, no cirrhosis, HCV viral load < 6 million copies/ml → Regimen 1 (HIV negative only) or 2 or 11
<input type="checkbox"/>	Treatment naïve, no cirrhosis, HCV viral load ≥ 6 million → Regimen 2 or 11
<input type="checkbox"/>	Treatment naïve, compensated cirrhosis → Regimen 2 or for Child-Pugh A ONLY, (contraindicated in Child-Pugh B or C) 11 or 13
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin ONLY), not cirrhotic → Regimen 2 or 11
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin ONLY), cirrhosis → Regimen 4 or for Child-Pugh A ONLY, (contraindicated in Child-Pugh B or C) 13
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin ONLY), cirrhosis, ribavirin ineligible** → Regimen 3
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin +/- protease inhibitor), no cirrhosis → Regimen 2
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin +/- protease inhibitor), compensated cirrhosis → Regimen 4, if ribavirin ineligible** → Regimen 3
<input type="checkbox"/>	Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN or simeprevir + sofosbuvir), no cirrhosis → Regimen 4
<input type="checkbox"/>	Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN or simeprevir + sofosbuvir), compensated cirrhosis → Regimen 5
<input type="checkbox"/>	Treatment experienced, any NS5A inhibitor (daclatasvir + sofosbuvir, ledipasvir + sofosbuvir or paritaprevir/ritonavir/ombitasvir + dasabuvir), non-cirrhotic → guidelines recommend awaiting new data
<input type="checkbox"/>	Treatment experienced, any NS5A inhibitor (daclatasvir+sofosbuvir, ledipasvir+sofosbuvir or paritaprevir/ritonavir/ombitasvir + dasabuvir), cirrhosis or urgent need for treatment → testing for resistance-associated variants is recommended with 24 week treatment with ribavirin unless contraindicated
<input type="checkbox"/>	Re-infection of allograft liver after transplant → Regimen 4 or, if ribavirin ineligible** → Regimen 3
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir → Regimen 19
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir, ribavirin ineligible** → Regimen 16
<input type="checkbox"/>	Decompensated cirrhosis, prior treatment with sofosbuvir → Regimen 20
<input type="checkbox"/>	Genotype 1b
<input type="checkbox"/>	Treatment naïve, no cirrhosis, HCV viral load <6 million copies/ml → Regimen 1(HIV negative only) or 2 or 12
<input type="checkbox"/>	Treatment naïve, no cirrhosis, HCV viral load ≥6 million → Regimen 2 or 12
<input type="checkbox"/>	Treatment naïve, compensated cirrhosis → Regimen 2 or for Child-Pugh A ONLY, (contraindicated in Child-Pugh B or C) 11 or 12
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin ONLY), not cirrhotic → Regimen 2 or 12

<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin ONLY), cirrhosis → Regimen 4 or for Child-Pugh A ONLY, (contraindicated in Child-Pugh B or C) 12
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin ONLY), cirrhosis, ribavirin ineligible** → Regimen 3
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin +/- protease inhibitor), no cirrhosis → Regimen 2
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin + protease inhibitor), compensated cirrhosis → Regimen 4, or if ribavirin ineligible** → Regimen 3
<input type="checkbox"/>	Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN or simeprevir + sofosbuvir), no cirrhosis → Regimen 4
<input type="checkbox"/>	Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN or simeprevir + sofosbuvir), advanced fibrosis or compensated cirrhosis → Regimen 5
<input type="checkbox"/>	Treatment experienced, any NS5A inhibitor (daclatasvir + sofosbuvir, ledipasvir + sofosbuvir or paritaprevir/ritonavir/ombitasvir + dasabuvir), non-cirrhotic → guidelines recommend awaiting new data
<input type="checkbox"/>	Treatment experienced, any NS5A inhibitor (daclatasvir + sofosbuvir, ledipasvir + sofosbuvir or paritaprevir/ritonavir/ombitasvir + dasabuvir), cirrhosis or urgent need for treatment → testing for resistance-associated variants is recommended with 24 week treatment with ribavirin unless contraindicated
<input type="checkbox"/>	Re-infection of allograft liver after transplant → Regimen 4 or, if ribavirin ineligible** → Regimen 3
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir → Regimen 19
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir, ribavirin ineligible** → Regimen 16
<input type="checkbox"/>	Decompensated cirrhosis, prior treatment with sofosbuvir → Regimen 20
<input type="checkbox"/>	Genotype 2
<input type="checkbox"/>	Treatment naïve, no cirrhosis → Regimen 6
<input type="checkbox"/>	Treatment naïve, compensated cirrhosis → Regimen 7
<input type="checkbox"/>	Treatment naïve, ribavirin ineligible** → Regimen 15
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin) → Regimen 7, 8 or 9
<input type="checkbox"/>	Treatment experienced (sofosbuvir + ribavirin) → Regimen 8, if IFN ineligible* → Regimens 16 or 17
<input type="checkbox"/>	Decompensated cirrhosis → Regimen 18
<input type="checkbox"/>	Re-infection of allograft liver after transplant, no or compensated cirrhosis → Regimen 18
<input type="checkbox"/>	Re-infection of allograft liver after transplant, no or compensated cirrhosis, ribavirin ineligible** → Regimen 16
<input type="checkbox"/>	Genotype 3
<input type="checkbox"/>	Regardless of prior treatment, with/without cirrhosis → Regimen 8
<input type="checkbox"/>	Treatment naïve, IFN* or ribavirin** intolerant, non-cirrhotic → Regimen 15
<input type="checkbox"/>	Treatment naïve, IFN intolerant*, cirrhosis → Regimen 9
<input type="checkbox"/>	Treatment naïve, ribavirin intolerant**, cirrhosis → Regimen 16
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin), ribavirin ineligible**, no cirrhosis → Regimen 15
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis, IFN ineligible → Regimen 17
<input type="checkbox"/>	Treatment experienced (sofosbuvir + ribavirin), IFN ineligible** → Regimen 17
<input type="checkbox"/>	Decompensated cirrhosis → Regimen 18
<input type="checkbox"/>	Re-infection of allograft liver after transplant, no or compensated cirrhosis → Regimen 18
<input type="checkbox"/>	Re-infection of allograft liver after transplant, no or compensated cirrhosis, RBV ineligible** → Regimen 16
<input type="checkbox"/>	Re-infection of allograft liver after transplant, decompensated cirrhosis → Regimen 21
<input type="checkbox"/>	Genotype 4
<input type="checkbox"/>	Regardless of prior treatment, no cirrhosis → Regimen 2, 8 or 14
<input type="checkbox"/>	Regardless of prior treatment, compensated cirrhosis → Regimen 2 or 8
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir → Regimen 19
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir, ribavirin ineligible** → Regimen 16
<input type="checkbox"/>	Decompensated cirrhosis, prior treatment with sofosbuvir → Regimen 20
<input type="checkbox"/>	Re-infection of allograft liver after transplant, no or compensated cirrhosis → Regimen 4
<input type="checkbox"/>	Re-infection of allograft liver after transplant, no or compensated cirrhosis, ribavirin ineligible** → Regimen 3
<input type="checkbox"/>	Genotype 5
<input type="checkbox"/>	Regardless of prior treatment → Regimen 2 or 8
<input type="checkbox"/>	Genotype 6
<input type="checkbox"/>	Regardless of prior treatment → Regimen 2 or 8
<input type="checkbox"/>	Hepatocellular Carcinoma and Awaiting Liver Transplant
<input type="checkbox"/>	Genotypes 1 or 4 → Regimen 4
<input type="checkbox"/>	Genotypes 2, 3 → Regimen 18 or 10

REGIMENS:

1. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily for 56 days (8 weeks) ☐
2. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily for 84 days (12 weeks) ☐
3. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily for 168 days (24 weeks) ☐
4. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily + weight-based ribavirin for 84 days (12 weeks) ☐
5. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily + weight based ribavirin for 168 days (24 weeks) ☐
6. Sovaldi (sofosbuvir) 400 mg daily + weight-based ribavirin for 84 days (12 weeks) ☐
7. Sovaldi (sofosbuvir) 400 mg daily + weight-based ribavirin for 112 days (16 weeks) ☐
8. Sovaldi (sofosbuvir) 400 mg daily + weight-based ribavirin + PEG-IFN weekly for 84 days (12 weeks) ☐
9. Sovaldi (sofosbuvir) 400 mg daily + weight based ribavirin for 168 days (24 weeks) ☐
10. Sovaldi (sofosbuvir) 400mg daily + weight-based ribavirin for up to 48 weeks or until liver transplant ☐
 - Will require documentation of diagnosis and reauthorization every 28 days
11. Viekira Pak (ombitasvir, paritaprevir, ritonavir 12.5/75/50 mg two tablets each morning + dasabuvir 250 mg twice daily with food) plus weight based ribavirin X 84 days (12 weeks) ☐
12. Viekira Pak (ombitasvir, paritaprevir, ritonavir 12.5/75/50 mg two tablets each morning + dasabuvir 250 mg twice daily with food) X 84 days (12 weeks) ☐
13. Viekira Pak (ombitasvir, paritaprevir, ritonavir 12.5/75/50 mg two tablets each morning + dasabuvir 250 mg twice daily with food) plus weight based ribavirin X 168 days (24 weeks) ☐
14. Technivie (ombitasvir, paritaprevir, ritonavir 25/150/100 mg) + weight-based ribavirin for 84 days (12 weeks) ☐
15. Daklinza (daclatasvir) 60mg[^] daily + Sovaldi (sofosbuvir) 400 mg daily X 84 days (12 weeks) ☐
16. Daklinza (daclatasvir) 60mg[^] daily + Sovaldi (sofosbuvir) 400 mg daily X 168 days (24 weeks) ☐
17. Daklinza (daclatasvir) 60mg[^] daily + Sovaldi (sofosbuvir) 400 mg daily + weight-based RBV X 168 days (24 weeks) ☐
18. Daklinza (daclatasvir) 60 mg[^] + Sovaldi (sofosbuvir) 400 mg daily and low dose RBV[#] X 84 days (12 weeks) ☐
19. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily + low dose ribavirin[#] for 84 days (12 weeks) ☐
20. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily + low dose ribavirin[#] for 168 days (24 weeks) ☐
21. Sovaldi (sofosbuvir) 400 mg daily + low dose ribavirin[#] for 168 days (24 weeks) ☐

[^] Dose of Daklinza (daclatasvir) MUST BE ADJUSTED with certain co-administered drugs (reduced to 30 mg daily with concurrent CYP3A4 inhibitors and increased to 90 mg daily with concurrent moderate CYP3A4 inducers)

[#] low dose ribavirin = 600 mg/day and increase as tolerated

OTHER: Please provide clinical rationale for choosing a regimen that is beyond those found within the current guidelines, or for selecting regimens other than those outlined above.

☐ Other drug regimen: please specify all drugs and include the dose and duration for each:

The following documentation must be submitted with initial request for consideration of approval:

<input type="checkbox"/> Active HCV infection verified by viral load within the last year	<input type="checkbox"/> HCV Genotype verified by lab Genotype: (circle) 1a 1b 2 3 4 5 6 <input type="checkbox"/> Metavir fibrosis score: _____ Date: _____ Method(s) used: _____
<input type="checkbox"/> Prescriber is, or has consulted with, a gastroenterologist, hepatologist, ID specialist or other Hepatitis specialist. Consult must be w/in the past year with documentation of recommended regimen.	<input type="checkbox"/> Documentation in provider notes (must be submitted) showing that member has had no abuse of alcohol and drugs for the previous 6 months. MUST submit urine drug screen for members with history of abuse of drugs other than alcohol. Counseling MUST be provided and documented regarding non-abuse of alcohol and drugs as well as education on how to prevent HCV transmission
<input type="checkbox"/> Patient is not receiving dialysis and has CrCl \geq 30mL/min (Sovaldi only) <ul style="list-style-type: none"> <input type="checkbox"/> Verified by lab results including a creatinine level within the past 6 months 	<input type="checkbox"/> Sovaldi: Current medication list that does NOT include: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifabutin, rifampin, rifapentine, St. John's Wort, or tipranavir/ritonavir <input type="checkbox"/> Harvoni: Current medication list that does NOT include: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifabutin, rifampin, rifapentine, St. John's Wort, ritonavir, tipranavir, Stribild, Crestor, H2 receptor antagonists above the following daily doses: famotidine 80 mg, ranitidine/nizatidine 600 mg or cimetidine 1600 mg; or PPIs above the following daily doses: esomeprazole 20 mg, lansoprazole or 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg

For ANY regimen that includes ribavirin

☐ **For women of childbearing potential** (and male patients with female partners of childbearing potential):

- ☐ Patient is not pregnant (or a male with a pregnant female partner) and not planning to become pregnant during treatment or within 6 months of stopping
- ☐ Agreement that partners will use two forms of effective non-hormonal contraception during treatment and for at least 6 months after stopping
- ☐ Verification that monthly pregnancy tests will be performed throughout treatment

☐ **For IFN-Intolerant*** (if GT3 and requesting regimen # 9 or for requests for other regimens, if applicable):

- ☐ Documented life-threatening side effects or potential side effects (i.e. history of suicidality)
- ☐ Decompensated cirrhosis (Child-Pugh >6)
 - Or Child-Pugh ≥ 6 if co-infected with HIV
- ☐ Blood dyscrasias:
 - Baseline neutrophil count $<1500/\mu\text{L}$, baseline platelets $<90,000/\mu\text{L}$ or baseline Hgb $<10\text{g/dL}$
- ☐ Pre-existing unstable or significant cardiac disease (e.g. history of MI or acute coronary syndrome)
- ☐ Other: _____

☐ **For Ribavirin-Intolerant**:**

- ☐ History of severe or unstable cardiac disease
- ☐ Pregnant women and men with pregnant partners
- ☐ Diagnosis of hemoglobinopathy (e.g., thalassemia major, sickle cell anemia)
- ☐ Hypersensitivity to RBV
- ☐ Baseline platelet count $< 70,000$ cells/mm³
- ☐ ANC < 1500 cells/mm³
- ☐ Hb < 12 gm/ml in women or <13 g/dl in men
- ☐ Other: _____

Patients with CrCl <50 ml/min (moderate or severe renal dysfunction, ESRD, HD) should have dosage reduced

By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in your medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.

Provider Signature: _____ **Date of Submission:** _____

***MUST MATCH PROVIDER LISTED ABOVE**